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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. CAMPIE, Plaintiff and Relator, v. GILEAD SCIENCES, INC., Defendant.	CASE NO. C-11-0941 EMC **DECLARATION OF GEORGE SCAVDIS IN SUPPORT OF THE UNITED STATES' MOTION TO DISMISS RELATORS' SECOND AMENDED COMPLAINT;** Date: June 20, 2019 Time: 1:30 p.m. The Honorable Edward M. Chen Courtroom 5, 17th Floor

DECLARATION OF GEORGE SCAVDIS

I, George Scavdis, declare:

1. I am an Assistant Special Agent in Charge at the United States Food and Drug Administration ("FDA"), Office of Criminal Investigations. Based on my review of FDA's records, I have personal knowledge of the matters set forth herein.

2. In 2008, Gilead submitted a Prior Approval Supplement (PAS) to allow the use of active pharmaceutical ingredient (API) from a new manufacturer (Synthetics China) in its finished drug products. In the PAS, Gilead committed to providing additional stability data when it became available. In March 2009, FDA conducted an on-site inspection of Synthetics China. As part of the inspection, Gilead disclosed that two validation batches of API did not meet the specifications for the drug's, but that changes were made to the process design and the validation was repeated and acceptable results were obtained. FDA did not issue a Form 483, having recorded no deficiencies with the manufacturing or testing operations at Synthetics China that warranted further action. In April 2009, Gilead submitted a PAS amendment with additional stability data. On May 8, 2009, FDA approved the PAS for Synthetics China.

3. Between January and February 2010, FDA inspected Gilead's San Dimas facility and identified certain violations of the Current Good Manufacturing Practice (cGMP) regulations. FDA discussed its findings with Gilead. FDA issued a Warning Letter on September 21, 2010. FDA evaluated the corrective actions that Gilead took in response to the Warning Letter. On August 4, 2011, FDA issued a letter to Gilead stating that those corrective actions appeared to address the violations identified in the Warning Letter.

4. In April 2011, FDA conducted a second on-site inspection of the Synthetics China facility. FDA did not issue a Form 483 based on the April 2011 inspection.

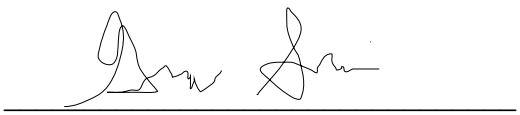
5. Between November 2011 and January 2012, Gilead submitted Field Alert Reports to FDA related to particulates in finished product at Gilead's Foster City facility. In June 2012, FDA inspected the Foster City facility and issued a Form 483 relating to cGMP deficiencies.

6. In March 2012, FDA requested additional information about validation and reprocessing of batches at Synthetics China, and received additional information from Gilead in April 2012. In March 2013, FDA conducted a third on-site inspection of the Synthetics China facility. FDA did not issue a Form 483 based on the March 2013 inspection.

7. In response to these inspections, FDA did not stop production at any Gilead facility or determine that any of Gilead's drug products needed to be recalled.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on March 27, 2019 in Charleston, SC



GEORGE SCAVDIS